

RECEIVED
OPPT CBIC

2014 JUN 27 PM 12: 22

Sanitized Copy

CBIC Control Number

360753

June 26, 2014

Via Federal Express

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Maternal Toxicity Study in Wistar Rats with and experimental pesticide

Dear Section 8(e) Coordinator:

[REDACTED] is submitting results of a Maternal Toxicity Study in Wistar Rats [CrI:WI(HAN)] with 3 [REDACTED], conducted by [REDACTED]. The test substance is an experimental pesticide.

The test substance was administered to groups of 10 presumed pregnant female Wistar rats via gavage from gestational day (GD) 6 to 19. On gestation day 20, the females were necropsied and the weights of the unopened uteri were determined. Contents of the uterus and fetuses were not examined.

This range-finding study was carried out with reference to the requirements of the following guidelines:

- EPA Health Effects Test Guidelines, OPPTS 870.3700: Prenatal Developmental Toxicity Study (Aug 1998)
- OECD Guideline for Testing of Chemicals; Proposal for updating Guideline 414: Prenatal Developmental Toxicity Study (22 Jan 2001)

The dose levels were: 1000 and 500 mg/kg body weight/day.

The following is a summary of the most relevant results:

1000 mg/kg bw/d

- One rat was found dead on GD 9
- All other rats were sacrificed moribund/premature on GD 9
- Unsteady gait (7 of 10 rats)
- Ataxia (1 of 10 rats)
- Semiclosed eyelid (1 of 10 rats)
- Abdominal respiration (1 of 10 rats)
- Salivation (9 of 10 rats)
- Increased water consumption (57%, GD 6-8)

COMPANY SANITIZED

Sanitized Copy

TSCA Confidential Business Information Center (7407M)

June 26, 2014

Page 2

- Reduced food consumption (-23%, GD 6-8)
- Body weight loss (GD 6-8)
- Macroscopic findings at necropsy:
 - Deposits in the forestomach (9 of 10 rats)
 - Margo plicatus of the forestomach thickened (5 of 10 rats)
 - Wall of the forestomach thickened (1 of 10 rats)
 - Focus at the glandular stomach (4 of 10 rats)

500 mg/kg bw/d

- Salivation (10 of 10 rats)
- Increased water consumption (20%, GD 6-19)

██████████ understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,